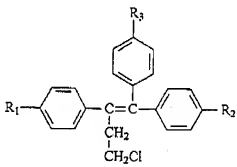
AMENDMENTS TO THE CLAIMS

Please add or amend the claims to read as follows, and cancel without prejudice or disclaimer to resubmission in a divisional or continuation application claims indicated as cancelled:

1. (Currently amended) A method of ~~suppressing, inhibiting, or~~ reducing the incidence of pre-malignant lesions of prostate cancer in a human, comprising the step of administering to the human a pharmaceutical composition comprising 60 mg of a compound represented by the structure of formula (I), its N-oxide, ester, pharmaceutically acceptable salt, hydrate, or any combination thereof:



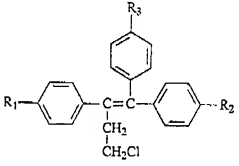
(I)

wherein R_1 and R_2, which can be the same or different, are H or OH; R_3 is $OCH_2CH_2NR_4R_5$, wherein R_4 and R_5, which can be the same or different, are H or an alkyl group of 1 to about 4 carbon atoms

wherein said pharmaceutical composition comprises 60 mg of the compound of formula (I).

2. (Currently amended) A method of treating a human with pre-malignant lesions of prostate cancer, comprising the step of administering to the human a pharmaceutical

composition comprising 60 mg of a compound represented by the structure of formula (I), its N-oxide, ester, pharmaceutically acceptable salt, hydrate, or any combination thereof:



(I)

wherein R_1 and R_2, which can be the same or different, are H or OH; R_3 is $OCH_2CH_2NR_4R_5$, wherein R_4 and R_5, which can be the same or different, are H or an alkyl group of 1 to about 4 carbon atoms.

3. (Original) The method according to claim 1 or 2, wherein said compound of formula (I) is toremifene, its N-oxide, ester, pharmaceutically acceptable salt, hydrate, or any combination thereof.

4. -6. (Canceled)

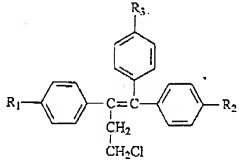
7. (Original) The method according to any of claims 1, 2, or 3, wherein the pre-malignant lesion is a precancerous precursor of prostate adenocarcinoma.

8. (Original) The method according to claim 7, wherein the precancerous precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

9. (Original) The method according to claim 8, wherein the prostate intraepithelial

neoplasia is high grade prostate intraepithelial neoplasia (HGPIN).

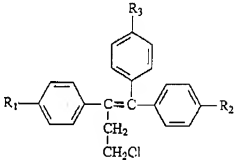
10. (Currently amended) A method of ~~suppressing, inhibiting, or~~ reducing the incidence of pre-malignant lesions of prostate cancer in a human comprising the step of administering to the human a pharmaceutical composition comprising ~~an analog or~~ 60 mg of a metabolite of a compound represented by the structure of formula (I), its N-oxide, ester, pharmaceutically acceptable salt, hydrate, or any combination thereof:



(I)

wherein R_1 and R_2, which can be the same or different, are H or OH; R_3 is $OCH_2CH_2NR_4R_5$, wherein R_4 and R_5, which can be the same or different, are H or an alkyl group of 1 to about 4 carbon atoms.

11. (Currently amended) A method of treating a human with pre-malignant lesions of prostate cancer, comprising the step of administering to the human a pharmaceutical composition comprising ~~an analog or~~ 60 mg of a metabolite of a compound represented by the structure of formula (I), its N-oxide, ester, pharmaceutically acceptable salt, hydrate, or any combination thereof:



(I)

wherein R_1 and R_2, which can be the same or different, are H or OH; R_3 is $OCH_2CH_2NR_4R_5$, wherein R_4 and R_5, which can be the same or different, are H or an alkyl group of 1 to about 4 carbon atoms.

12. (Original) The method according to claim 10 or 11, wherein the compound is 4-chloro-1,2-diphenyl-1-[4-[2-(N-methylamino) ethoxy] phenyl]-1-butene; 4-chloro-1,2-diphenyl-1-[4-[2-(N,N-diethylamino) ethoxy]phenyl]-1-butene; 4-chloro-1,2-diphenyl-1-[4 (aminoethoxy)]-1-butene; 4-chloro-1-(4-hydroxyphenyl)-1-[4-[2-(N,N-dimethylamino) ethoxy] phenyl]-2-phenyl-1-butene; 4-chloro-1-(4-hydroxyphenyl)-1-[4-[2-(N-methylamino)ethoxy] phenyl]-2-phenyl-1-butene; or 4-chloro-1,2-bis(4-hydroxyphenyl)-1-[4-[2-(N,N-dimethylamino)ethoxy]phenyl]-1-butene.

13. -15. (Canceled)

16. (Original) The method according to any of claims 10 or 11, wherein the pre-malignant lesion is a precancerous precursor of prostate adenocarcinoma.

17. (Original) The method according to claim 16, wherein the precancerous

precursors of prostate adenocarcinoma is prostate intraepithelial neoplasia (PIN).

18. (Original) The method according to claim 17, wherein the prostate intraepithelial neoplasia is high grade prostate intraepithelial neoplasia (HGPIN).

19. (Currently amended) The method according ~~to any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition further comprises a pharmaceutically acceptable carrier.

20. (Original) The method according to claim 19, wherein said carrier is selected from the group consisting of a gum, a starch, a sugar, a cellulosic material, and mixtures thereof.

21. (Currently amended) The method according to ~~any of~~ claim[[s]]1[[,]] or 10, wherein said administering comprises subcutaneously implanting in said human a pellet containing said pharmaceutical composition.

22. (Original) The method according to claim 21, wherein said pellet provides for controlled release of said pharmaceutical composition over a period of time.

23. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said administering comprises intravenously, intraarterially, or intramuscularly injecting into said human said pharmaceutical composition in liquid form.

24. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said administering comprises orally administering to said human a liquid or solid preparation containing said pharmaceutical composition.

25. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10,

wherein said administering comprises topically applying to skin surface of said human said pharmaceutical composition.

26. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition is selected from the group consisting of a pellet, a tablet, a capsule, a solution, a suspension, an emulsion, an elixir, a gel, a cream, and a suppository.

27. (Original) The method according to claim 26, wherein said suppository is a rectal suppository or a urethral suppository.

28. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition is a parenteral formulation.

29. (Original) The method according to claim 28, wherein said parenteral formulation comprises a liposome.

30. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition is administered once daily.

31. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition is administered twice daily.

32. (Currently amended) The method according to ~~any of~~ claim[[s]] 1[[,]] or 10, wherein said pharmaceutical composition is administered thrice daily.